PTO/SB/08a (05-03)
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e for form 1449A/PTO

Sheet

THE PROENT INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

	Complete if Known
Application Number	10/757,077
Filing Date	January 14, 2004
First Named Inventor	Lance E. Steward
Art Unit	Not Yet Assigned
Examiner Name	Not Yot Assigned Hayes
Attorney Docket Number	ALLE0014-103 (17335CIP3)

			U.S. PATENT (DOCUMENTS	
Examiner Cite Document		Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant
Initials *	No.1	Number - Kind Code ² (if known)	MM-OD-YYYY	Cited Document	Passages or Relevant Figures Appear
RH	AA	US-6,458,365	10/01/2002	Aoki, et al	
1	AB	US- 5,766,605	06/16/1998	Sanders et al	
	AC	US- 5,714,468	02/03/1998	Dao	
	AD	US- 6,464,986	10/15/2002	Aoki et al	
	AE	US- 6,113,915	09/05/2000	Aoki et al	
	AF	US- 6,306,403	10/23/2001	Donovan	
	AG	US- 6,299,893	10/09/2001	Schwartz et al	,
	AH	US- 5,670,484	09/23/1997	Binder	
	Al	US- 6,423,319	07/23/2002	Brooks et al	1
	AJ	US- 6,139,845	10/31/2000	Donovan	
	AK	US- 6,143,306	11/07/2000	Donovan	
	AL	US- 5,437,291	08/01/1995	Pasricha et al	
	AM	US- 6,365,164	04/02/2002	Schmidt	
	AN	US- 6,063,768	05/16/2000	First	
	AO	US- 6,395,277	05/28/2002	Graham	
1	AP	US- 6,265,379	07/24/2001	Donovan	
	AQ	US- 6,358,513	03/19/2002	Voet et al	
Î	AR	US- 6,328,977	12/11/2001	Donovan	
\sqrt{I}	AS	US- 6,306,423	10/23/2001	Donovan	
_ V	AT	US- 6,312,708	11/06/2001	Donovan	

	FOREIGN PATENT DOCUMENTS							
Examiner	0.11	Foreign Patent Document		Name of Palentee or	Pages, Columns, Lines,			
Initials*	Cite No.1	Country Code ³ - Number ⁴ - Kind Code ⁶ (if known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶		
RH	BD	WO94/15629	07/21/94	AS Synapse Biol.				
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Examiner Signature	/Robert Hayes/	Date Considered	01/03/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional), 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to

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Substitu	te for form 1449A/P	PTO	•		Complete if Known
				Application Number	10/757,077
INF	DRMATIO	n dis	CLOSURE	Filing Date	January 14, 2004
STA	TEMENT	BY AI	PPLICANT	First Named Inventor	Lance E. Steward
				Art Unit	Not Yet Assigned .
	(Use as many s	sheets as	necessary)	Examiner Name	Not yet Assigned
Sheet	2	of	7	Attorney Docket Number	ALLE0014-103 (17355CIP3)

			U.S. PATENT D	OCUMENTS	
Evaminer	Examiner Cite	Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant
Initials *	No.1	Number - Kind Code ² (<i>if known</i>)	MM-DD-YYYY		Passages or Relevant Figures Appear
RH	AU	US-5,053,005	10/01/1991	Borodic	
ı	AV	US- 5,174,468	02/03/1998	Binder	
	AW	US- 5,721,215	02/24/1998	Aoki et al	
	AX	US- 5,989,545	11/23/1999	Foster et al	
	AY	UE 6,413,015	00/05/0000	Achi et al	DUPLICATE CITATIO
	AZ	US- 5,939,070	08/17/1999	Johnson et al	
	BA	US- 3,700,000	88/18/1888	Condors at ai	
V	BB	US 5,437,301	08/14/1005	Pacricha et al	
W	BC	US- 4,932,938	06/12/1990	Dykstra et al	
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		FOREIGN PA	TENT DOCU	MENTS		
Superior City	Cite	Foreign Patent Document		Name of Patentee or	Pages, Columns, Lines,	
Examiner Initials*	No.1	Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T°
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Examiner Signature	/Robert Hayes/	Date Considered	01/03/2007

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the appropriate symbols as indicated on the document under vviPO Standard S1. To it possible. Applicant to to prace a direct minimal result in the control of the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitut	o for form 1449E	I/PTO			Complete if Known
	O 5 5 6 T 1 C	DIO		Application Number	10/757,077
			CLOSURE	Filing Date	January 14, 2004
STA	TEMENT	BY A	PPLICANT	First Named Inventor	Lance E. Steward
				Art Unit	Not Yet Assigned
	(Use as man	y sheets as	necessary)	Examiner Name	Not Yet Assigned
Sheet	3	of	7	Attorney Docket Number	ALLE0014-103 (17355CIP3)

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	т²
RH	BE	ADENIS, et al., J. Fr. Ophthamol. (1990) 13:259-264. (Abstract only in English)	
	BF	BINZ, et al., J. Biol. Chem. (1990) 265:9153-9158.	
	BG	BLITZER, et al., Ann. Otol. Rhinol Laryngol. (1985) 94:591-594.	
	ВН	BRIN, et al., Advances in Neurology, Vol. 50: Dystonia 2 (1988), pp. 599-608.	
	Bł	TENSI DI BELLO, et al., Eur. J. Biochem. (1994) 219:161-169.	-
$\overline{\mathbf{V}}$	ВЈ	COHN, et al., Neurology (1987) 37 (3 Supp. 1):123-124. (abstract only)	
10 CO	PУ	DARCOW, et al., J. Cell Biol. (1000) 142:010-022.	
in pa	rent		
RH	BL	ELSTON, et al., Br. J. Opthamol. (1985) 69:718-724.	
]	ВМ	FAUSI, et al., *Harrisen's Principles of Internal Medicine, 14th ed., (1998) McGraw Hill. no copy	
	BN	ELSTON, et al., Br. J. Opthamol. (1985) 69:891-896.	-
$\overline{\mathbf{A}}$	ВО	GALLI, et al., Cell (1998) 9:1437-1448.	

Examiner		Date	01/03/2007
Signature	/Robert Haves/	Considered	01/03/2007

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1 Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALLE0014-103 (17335CIP3)

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Substitute for form 1449B/PTO Complete if Known Application Number 10/757,077 INFORMATION DISCLOSURE Filing Date January 14, 2004 STATEMENT BY APPLICANT First Named Inventor Lance E. Steward Art Unit Not Yet Assigned (Use as many sheets as necessary) Examiner Name Not Yet Assigned

Attorney Docket Number

of | 7

Sheet

-		NON PATENT LITERATURE DOCUMENTS	,
Examiner Cite No.1			
RH	вР	JANCOVIC, et al., Neurology (1987) 37:616-623.	
no copies	BQ	**************************************	
provid	ed _R	KGZAKI, et al., d. Med. Sci. Blol. (1801) 34:01-98.	
	BS	LASY, ct al., Nat. Ovuct. Dict. (1999) 5.998-992.	
RH	ВТ	LI, et al., Biochemistry (1994) 33:7014-7020.	
1	вυ	MAISEY, et al., Eur. J. Biochem. (1988) 177:683-691.	
	BV	MARTINEZ-ARCA, et al., J. Cell Biol. (2000) 149:889-899.	
	вw	MILTON, et al., Biochemistry (1992) 31:8799-8809.	
V	вх	MINTON, in Clostridial Neurotoxins: the molecular pathogenesis of tetanus and botulism, Montecucco, ed., Springer Verlag, NY, 1995, pp. 161-194.	
no cor	ВУ	PEDEN, of al., J. Biol. Cham. (2001) 270.49105-49107.	
RH	BZ	SWAIN, et al., Peptide Res. (1993) 6:147-154.	

Examiner Signature	/Robert Hayes/	Date Considered	01/03/2007
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Substitute for form 1449B/PTO Complete if Known Application Number 10/757.077 INFORMATION DISCLOSURE Filing Date January 14, 2004 STATEMENT BY APPLICANT First Named Inventor Lance E. Steward Art Unit Not Yet Assigned (Use as many sheets as necessary) Examiner Name Not Yet Assigned Sheet of 7 Attorney Docket Number ALLE0014-103 (17355CIP3)

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	τ²
RH CA		ZHOU, et al., Biochemistry (1995) 34:15175-15181.	
1	СВ	SHIN, et al., J. Biol. Chem. (1991) 266:10658-10665.	
	СС	RASIBORSKA and CHARLTON, Can. J. Physiol. (1999) 77:679-688.	
	CD	ERDAL, et al., Arch. Pharmacol. (1995) 351:67-78.	
	CE	RAGONA, et al., The Larangyscope (1999) 109:1344-1346.	
	CF	NAUMANN, et al., Eur. J. Neurol. (1999) 6;S111-S115.	
	CG	KELLER, et al., FEBS Lett. (1999) 456:137-142.	
	СН	DIETRICH, et al., J. Cell. Biol. (1997) 138:271-281.	
	CI	GEISLER, et al., J. Biol. Chem. (1998) 273:21316-21323.	
	ငၪ	TAN, et al., J. Biol. Chem. (1998) 273:17351-17360.	
$\overline{\Psi}$	ск	LIU, et al., Trends Cell Biol. (1999) 9:356-363.	

Signature /Robert Hayes/ Considered 01/03/2007	Examiner Signature	/Robert Hayes/	Date Considered	01/03/2007
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Substitute	for form 1449	B/PTO			Complete if Known
	D			Application Number	10/757,077
			CLOSURE	Filing Date	January 14, 2004
STAT	STATEMENT BY APPLICANT			First Named Inventor	Lance E. Steward
				Art Unit	Not Yet Assigned
(Use as many sheets as necessary)			necessary)	Examiner Name	Not Yet Assigned
Sheet	6	of	7	Attorney Docket Number	ALLE0014-103 (17355CIP3)

Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	τ²
RH	CL	CAI and SINGH, Biochemistry (2001) 40:4693.	
1	СМ	TIKKANEN, et al., Traffic (2000) 1:631-640.	
	CN	RAPAPORT, et al., EMBO J. (1998) 17:2148-2155.	
	со	MIRANDA, et al., JBC Papers in Press (2001) 1-35.	
	СР	COWLES, et al., Cell (1997) 91:109-118.	
	co	AOKI, et al., J. Neurol. (2001) 248 (Supp 1):3-10.	
	CR	AOKI, Toxicon. (2001) 12:1815-1820.	
	cs	no date/ no page #s/ no yr	
	СТ	WIEGAND, et al., Nauny Schmiedberg's Arch. Pharmacol. (1976) 292:	
	cu_	HABERMAN, Nauny Schmiedberg's Arch. Pharmacol. (1974) 281:	
\forall	cv ·	THOMPSON, et al., Eur. J. Biochem. (1990) 189:73.	

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Examiner Signature	/Robert Hayes/	Date Considered	01/03/2007

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Substitu	ite for form 144	9B/PTO			Complete if Known
11154		1011 01	201 001105	Application Number	10/757,077
			SCLOSURE	Filing Date	January 14, 2004
STA	TEMEN	IT BY A	PPLICANT	First Named Inventor	Lance E. Steward
				Art Unit	Not Yet Assigned
	(Use as m	any sheets a	s necessary)	Examiner Name	Not Yet Assigned
Sheet	7	of	7	Attorney Docket Number	ALLE0014-103 (17355CIP3)

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	cw	duplicate citation	
RH	сх	ARNON, et al., "Botulinum toxin as a biological weapon: medical and public health management," JAMA (2001) 285:1059-1070.	
1	СҮ	ESWARAMOORTHY, et al., "A novel mechanism for Clostridium botulinum neurotoxin inhibition," Biochemistry (2002) 41:9795-9802.	
	cz	AOKI, et al., "Is the light chain subcellular localization an important factor for Botulinum neurotoxin duration of action?," Naunyn Schmiedebergs Arch. Pharmacol. (2002) 385 (Suppl 2):R10.	
	DA	FERNANDEZ-SALAS, et al., "Localization of BoNT light chains in neuronal and non-neuronal cell lines, implications for the duration of action of the different serotypes," Naunyn Schmiedebergs Arch. Pharmacol. (2002) 365 (Suppl 2):R19.	
V	DB	STEWARD, et al., "BoNT/A light chain and the dileucine motif: potential implications for light chain localization and neurotoxin duration of action," Naunyn Schmiedebergs Arch. Pharmacol. (2002) 385 (Suppl 2):R44.	

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		NON PATENT LITERATURE DOCUMENTS	
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RH	B1	FERNANDEZ-SALAS, et al., "Plasma Membrane Localization Signals in the Light Chain of Botulinum Neurotoxin," Slide presentation at USAMROD, January, 2004.	
1	B2	FERNANDEZ-SALAS, et al., "Plasma membrane localization signals in the light chain of botulinum neurotoxin," Proc. Natl. Acad. Sci. USA (2004) 101:3208-3213.	
V	В3	FERNANDEZ-SALAS, et al., "Is the light chain subcellular localization an important factor in Botulinum toxin duration of action?" Movement Disorders (2004) 19:S23-S34.	
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Examiner Signature	/Robert Hayes/	Date Considered	01/03/2007	

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LIST OF ART CITED BY APPLICANT

dr. and	<u> </u>	
ATTY. DOCKET	C: 17355-CIP3 (BOT)	SERIAL NO.: 10/757,077
APPLICANT:	LANCE E. STEWARD, et al.	TITLE: CLOSTRIDIAL NEUROTOXIN COMPOSITIONS AND MODIFIED CLOSTRIDIAL NEUROTOXINS
FILING DATE:	JANUARY 14, 2004	GROUP: 1649

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
RH	AA	2003/219462A1	11/27/2005	STEWARD et al.	424	239.1	06/04/2002
RH	AB	2003/027752A1	02/06/2003	STEWARD et al.	514	12	07/20/2001
	AC						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
RH	BA	WO 02/08268A2	01/31/2002	PCT	C07K	14/33	Y
	BB						

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

RH CA		Fernandez-Salas, E., et al., <i>Plasma membrane localization signals in the light chain of botulinum neurotoxin serotype A</i> , Society for Neuroscience Abstract Viewer and Itinerary Planner, Vol. 2003; pages Abstract No. 9.2				
	СВ	Foran, Patrick G., et al., Evaluation of the therapeutic usefulness of botulinum neurotoxin B, C1, E, and F compared with the long lasting type A. Basis for distinct durations of inhibition of exocytosis in central neurons, Journal of Biological Chemistry, Vol. 278, No. 2, 10 January 2003, pp. 1363-1371				
	CC	Wang Xingmin, et al., <i>Genetic analysis of type E botulinum toxin-producing Clostridium butyricum strains</i> , Applied and Environmental Microbiology, vol. 66, no. 11, November 2000, pp. 4992-4997				
	CD	Fernandez-Salas, E., et al., <i>Plasma membrane localization signals in the light chain of botulinum neurotoxin</i> , Proceedings of the National Academy of Sciences of the United States of America, 2 March 2004, vol. 101, no. 9, pp. 3208-3213				
	CE					
	CF					
	CG					

	/Robert Hayes/		/ /
XAMINER	•	DATE CONSIDERED	01/03/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.